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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,116	08/30/2000	A. Charles Morgan JR.	180042.418C2	6638

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/654,116	MORGAN ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment and declaration filed 1-8-04 has been entered into the record. Claims 19, 21-23 are pending and under examination, all other claims having been canceled.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Maintained

The rejection of claims 19 and 21 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for reasons made of record in the last office action.

Applicants arguments and declaration have been carefully considered but are not persuasive. The claims are drawn to a monoclonal antibody that (a) binds to a vitamin B12 binding site on TcII (b) inhibits cellular uptake of vitamin B12 and (c) is growth blocking. Applicant and Declarant argues that one skilled in the art could assay for such using the assays of the specification. Applicants argue that antibodies that bind a functional region of a polypeptide can be readily accomplished by functional assays. This is not persuasive, Applicants functional assays described in Example 9, do not measure the binding of the antibody to the vitamin B12 binding site. They measure the functional blocking vitamin B12 to TcII. As previously set forth, this functional assay is does not distinguish between antibodies that non-specifically inhibit vitamin B-12 binding by mere steric inhibition and those that bind the actual vitamin B12 binding site. Therefore, the assay of the specification does not detect binding to the vitamin B12 binding such,

it merely detects binding to TcII that results in inhibition of vitamin B12 binding. One skilled in the art can not extrapolate the specifically claimed binding property, binding to the vitamin B12 binding site, from this assay. The binding site is not disclosed in the assay of Example 9. Applicants arguments are not commensurate in scope with the claims. Applicants are not claiming an antibody that binds TcII and inhibits binding of vitamin B12. This is all that the alleged functional assay can determine. It can not determine the binding site of the antibody. The concept of binding outside of the actual binding site and blocking by steric hindrance is a concept that Applicants readily admit to in the specification as it relates to the interaction of the TcII/Vitamin B12 and its cognate receptor (see specification page 3, lines 33-36). Therefore, Declarant and Applicants are incorrect in the ability of the functional readout of the inhibition of binding assay to identify the site that the antibody binds as the vitamin B12 binding site. Such, the specificity of interaction of the antibody with particular residues in TcII can not be extrapolated from the functional assay as asserted by Applicant and Declarant. This specification does not teach how to make antibodies that bind the Vitamin B 12 binding site on TcII. The binding site on TcII is not identified in the specification, nor is any assay developed or contemplated that assays for antibodies that bind this undisclosed site. Applicants pointing to the skill in the art to provide for these deficiencies is not persuasive, because the art does not teach the actual binding site of vitamin B12 on TcII. Applicants' arguments and the Declaration of Dr. Quadros are not persuasive.

The rejection of claims 19 and 21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons made of record in the last office action.

Applicants arguments have been carefully considered but are not persuasive. Applicants argue that one skilled in the art would readily understand that the antibodies bind to a specific region of TcII, namely the vitamin B12 binding site and that antibodies having this characteristic could be readily screened. This is not persuasive, the vitamin B12 binding site on TcII is not described in this specification nor is it described in the art. Applicants assay in the specification does not assay for the binding site on TcII, it assays for blocking binding of vitamin B12 to human TcII. This assay, does not and can not tell one skilled in the art if that antibody, which is much larger than vitamin B12 binds the claimed B12 binding site or binds "near" the site as to non-specifically sterically hinder the binding of B12 to its specific binding site. The claims do not convey the argued generic concept of a monoclonal antibody that blocks binding of vitamin B12 to human TcII. Applicants assays do not determine binding to the specific the binding site as instantly claimed. Applicants arguments in regard to a generic TcII binding assay are irrelevant. The claims require that the antibody bind the Vitamin B 12 binding site on TcII and this binding site as it relates to specific residues on TcII is not described in the specification or art and as such, the skilled artisan would not be able to ascertain if their monoclonal antibody infringed on the instantly claimed monoclonal antibody or not. While it is routine to assay for a claimed functional characteristic, the claims are not presented by mere functional characteristic, they have a specifically recited binding property. There are two specific requirements that must be met by the claimed monoclonal antibody (a) binding to the vitamin B12 binding site on TcII, (b) inhibiting the cellular uptake of vitamin B12 and (c) growth blocking. Mere presentation of arguments that you can assay for the second claimed function is irrelevant to the issue. This issue here is, does the skilled artisan know the metes and bounds of the vitamin B12 binding site on TcII. The answer is clearly no. Neither this specification, nor the art teaches

such. As such, one could not use any generic TcII binding assay for such, because mere binding does not distinguish between binding the specific Vitamin B12 binding site on TcII and any other site. No assay for monoclonal antibodies that specifically bind the Vitamin B 12 binding site on TcII is described or disclosed in this specification.

The rejection is maintained across this issue only. The issue of antagonizing or modulating is moot in view of the cancellation of this material from the claims.

New Rejections Based on Amendment

Claims 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification fails to provide conception by way of written description for the now claimed subject matter. The specification only conceives of monoclonal antibodies that bind a vitamin B12 binding site on transcolbalmin II (TcII) and inhibits the cellular uptake of vitamin B12. The specification does not provide written description for the new genus of monoclonal antibodies that inhibit the binding to vitamin B12 to TcII, inhibit the cellular uptake of vitamin B12 and blocks cell growth. Applicants have generically pointed to the entirety of the specification to provide support for the now claimed monoclonal antibody. This is not persuasive, Applicants are mixing and matching concepts for the anti-receptor antibody with the specific anti-TcII monoclonal antibody that bind a vitamin B12 binding site on transcolbalmin II (TcII) to arrive at a new subgenus that lacks conception in the specification as filed. This issue is best resolved by Applicants pointing to the

specification by page and line number where explicit written description support can be found in the specification as filed. The instantly claimed monoclonal antibodies do not find implicit support in Figure 5, because these antibodies only have the ability to bind human TcII and are not characterized as blocking cell growth. As such, a new subgenus of monoclonal antibodies are claimed herein, and this subgenus does not have written description in the specification as originally filed.

New Rejections

Claims 19, 21, 22 and 23 are rejected under 35 U.S.C. 102(a) as being clearly anticipate by Quadros et al (Blood et al, 10(Suppl 1)p 125A, December 1-5, 1995.

Quadros et al teach monoclonal antibodies that block vitamin B 12 binding to apo TcII and decrease the uptake of vitamin B 12 (see entire abstract). Quadros et al teach that these monoclonal antibodies bind "at or near" the vitamin B12 binding site on apo TcII.

With respect to the claim for priority under 35 USC 120, it is noted that to be entitled to claim priority to an earlier filed United States Patent Application, the claims must have specific written description and must be enabled (i.e. must comply with 35 USC 112, first paragraph). The instant claims either do not comply with 35 USC 112, first paragraph in any of the earlier filed Applications for which priority is claimed in view of the new matter rejection set forth *supra* for claims 22 and 23 and the enablement rejection for claims 19 and 21.

Status of Claims

All claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patricia A. Duffy

Primary Examiner

Art Unit 1645